REMARKS

Claims 1-35 are currently pending in the application. Claims 14-35 are withdrawn. However, Applicants note that there is some confusion about whether claim 35 is under consideration. Applicants assume that claim 35 is not currently under consideration. Clarification is requested should their understanding on this issue be incorrect.

Claim 1 has been amended to further define the pharmaceutical composition contained by the article of manufacture. Claim 12 has been cancelled, without prejudice, in view of the amendments to claim 1. Claims 8, 9, 10, 11, and 13 have been amended for syntax and logical consistency in view of amendments to claim 1. Accordingly, in view of the foregoing amendments, claims 1-11 and 13 are before the Examiner for consideration.

The abstract and title of the invention have been amended to more directly describe the invention to which the pending claims are directed.

Applicants note the provisional obviousness-type double patenting rejection of claims 1-13. Applicants respectfully request that this provisional obviousness double patenting rejection be held in abeyance until such time that it is clear the claims of co-pending application No. 10/410322 or co-pending application No. 10/489807 will be patented before the claims of the subject application.

Claims 6 and 7 are rejected under 35 USC§112, first paragraph, as not complying with the written description requirement. Applicants respectfully traverse. The Office Action rejects the use of the language "facilitating substances" on the grounds that such substances are only defined specifically by what they do and not what they actually are. Applicants assert that substances facilitating transport across the blood-brain barrier were known at the time of filing the subject application, and one skilled in the art would undoubtedly appreciate the substances to which claim 6 or 7 refers. For example, before the filing date of the subject application, it was well documented that stimulation of the

protein kinase C (PKC) pathway increases barrier permeability, including the transport of amino acids across the blood-brain barrier. This is evidenced by the following reports:
Lynch JJ, Ferro TJ, Blumenstock FA, Brockenauer AM, Malik AB. 1990. Increased endothelial albumin permeability mediated by protein kinase-C activation. J. Clin Invest 85: 1991-1998.
Rubin LL, Staddon JM. 1999. The cell biology of the blood-brain barrier. Annu Rev Neurosci 22: 11-28.
Ermisch A, Landgraf R, Brust P. Kretzschmar R, Hess J. 1988. Peptide receptors of the cerebral capillary endothelium and the transport of amino acids across the blood-brain barrier. In: Rakic L, Begley DJ, Davson H, Zlokovic BV, editors. Peptide and amino acid transport mechanisms in the central nervous system. London: Macmillan. P51-54.
Accordingly, as the above cited papers show, substances capable of facilitating transport across the blood-brain barrier were known as of the filing date of the subject application. Therefore, it is reasonable for applicants to use the term facilitating substances to refer to substances known in the art to facilitate such transport. What is critical is that the applicants were aware that such substances existed and that they were described in the specification and claims in such a manner as to convey possession of such substances. In view of the foregoing, applicants respectfully request the reconsideration and withdrawal of this 35 USC §112, first paragraph rejection.

Claims 1-13 are rejected under 35 USC §103(a) as being obvious over Liechty et al. Applicants believe that the amendments to claim 1 above obviate this rejection. Claim 1 has been amended to replace the transitional phrase "comprising" with the transitional phrase "consisting essentially of." The Aminosyn RF infusion referred to in Lielchty includes high concentrations of many non-aromatic amino acids, specifically large neutral amino acids. The provision of an expansive amino acid solution may serve a nutritional purpose, but would not be appropriate for the careful administration of certain aromatic amino acids, and/or combinations of specific aromatic amino acids, for the purpose of treating a disease or condition which is related to or which can be affected by modulation of glutamate receptor activity. Indeed, the Aminosyn RF composition taught by Liechty et al., since it contains high concentrations of large neutral amino acids, likely

would interfere with the desired transport of the aromatic amino acids across the blood-brain barrier. That is, the large neutral amino acids would compete for the blood-brain barrier transporters. Accordingly, the inclusion of high concentrations of a broad variety of amino acids materially changes the nature of the composition. Thus, the Liechty et al. composition is distinguished from the compositions claimed in amended claim 1. As claims 2-11 and 13 are construed to contained all the limitations of the independent base claim 1, the Liechty et al. reference is distinguished from such dependent claims as well. Therefore, Applicants respectfully request the reconsideration and withdrawal of this 35 USC §103(a) rejection.

Claims 1, 2, 4, 5, 8-13 and 35 are rejected under 35 USC §102(b) as being anticipated by Liechty et al. Applicants assert that the amendments to claim 1 obviate this rejection and incorporate the remarks made in rebuttal of the 103 obviousness rejection above based on the same reference. The Aminosyn RF composition taught by Liechty et al. does not teach a composition consisting essentially of an aromatic amino acid. The Aminosyn RF composition contains high concentrations of non-aromatic amino acids which change the nature of the composition from that of a composition consisting essentially of an aromatic amino acid. The presence of high concentrations of large neutral amino acids competes for blood-brain barrier transporters, and therefore interferes with the proper administration and desired effect of the composition as claimed in amended claim 1. Furthermore, nowhere does Leichty et al. teach that it would be desirous to remove certain amino acid from the aminosyn composition, and there is no other cited motivation to do so to achieve a composition suitable for accurate administration of aromatic amino acids. Dependent claims 2, 4, 5, and 8-13 are construed to contain all the limitations of the base claim 1. Thus, the amendments to claim 1 obviate this rejection as it applies to claims depending therefrom. Applicants respectfully request the reconsideration and withdrawal of this 35 USC §102(b) rejection.

Claims 1 and 8-13 are rejected under 35 USC §102(b) as being anticipated by the Merck Index. Applicants traverse. Independent claim 1 recites a pharmaceutically accepted carrier as one of the elements of the claimed composition. Applicants urge that

the cited Merck Index pages do not teach the combination of an aromatic amino acid with a pharmaceutically acceptable carrier as necessary to satisfy the requirements for anticipation. Claims 8-13 are construed to contain the limitation of claim 1. Applicants respectfully request the reconsideration and withdrawal of this 35 USC §102(b) rejection.

All grounds for rejection or objection having been addressed and overcome herein, it is respectfully urged that this application is in condition for allowance. Applicants request that the Examiner call the undersigned if clarification is needed on any aspect of this Reply, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application.

Respectfully submitted,

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CERTIFICATE OF MAILING

I HEREBY CERTIFY that this RESPONSE is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450 on this 12th day of December 2005.

Alicia Hoffman